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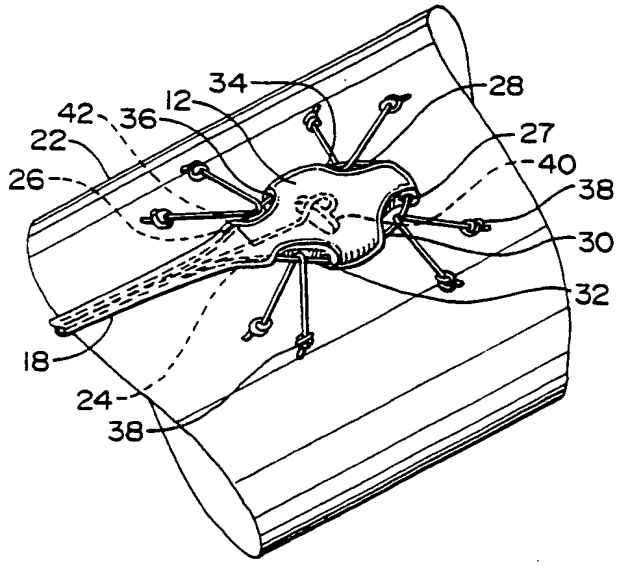

(57) Abstract

A removable implanted device (10) is provided which monitors the blood flow in a vessel (22) and can be removed through the insertion wound (20) without additional surgery. The device has an elongated probe body (12) which contains a Doppler-type ultrasonic transducer (40) attached to the probe body at an angle so as to enable monitoring of blood flow when attached to the vessel (22). The device has a flexible tube (18) which extends out of the body through the insertion wound (20). The device is held in place against the vessel (22) by sutures (38) which are secured to the probe body (12) by a suture attachment wire (24, 26) which may be bent or looped to form two substantially equal lengths (24, 26). Alternate embodiments use a release wire (62) or a balloon (70) to secure the sutures (38) to the probe body (12).

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Removable Implanted Device

Background Of the Invention

1. Field Of The Invention

This invention relates to a removable implanted device, and more particularly, to a ultrasound sensor for measuring blood flow which can be implanted, then removed from the patient without reopening the implant wound.

2. Description Of The Related Art

The art described in this section is not intended to constitute an admission that any patent, publication or other information referred to herein is "prior art" with respect to this invention, unless specifically designated as such. In addition, this section should not be construed to mean that a search has been made or that no other pertinent information as defined in 37 C.F.R. §1.56(a) exists.

U.S. Patent No. 3,661,146, entitled "Transducer Arrangement For Measuring Blood Flow", issued May 9, 1972 to Peronneau, is directed to a transducer for measuring the speed and flow of blood. The transducer is fixed to the vessel with a band of dacron which is sutured shut. This device does not allow for removal without reopening the wound.

U.S. Patent No. 4,313,448, entitled "Myocardial Sutureless Lead", issued February 2, 1982 to Stokes, is directed to a device which anchors itself in tissue using a barbed end. This device does not utilize sutures in conjunction with a wire to allow for removal without reopening the wound.

U.S. Patent No. 4,355,643, entitled "Vacuum Cup Doppler Flow Transducer And Method For Using Same", issued October 26, 1982 to Laughlin, is directed to a device which uses a suction cup to create a vacuum, and thereby attach the device to the vessel.

U.S. Patent No. 4,541,433, entitled "Cardiac Output Monitor", issued September 17, 1985 to Baudino, is directed to a device which uses a pair of fixation wires, which puncture the vessel and secure the instrument to the vessel.

U.S. Patent No. 4,671,295, entitled "Method For Measuring Cardiac Output", issued June 9, 1987 to Abrams, is directed to a device which does not require surgery. This device is inserted through the nasal or oral cavity.

U.S. Patent No. 4,722,347, entitled "Apparatus For Measuring Cardiac Output", issued February 2, 1988 to Abrams, is similar to U.S. Patent No. 4,671,295.

U.S. Patent No. 4,823,800, entitled "Implantable Ultrasonic Probe And Method Of Manufacturing The Same", issued April 25, 1989 to Compos, is directed to a device which may be removed without a complex procedure.

U.S. Patent No. 4,915,113, entitled "Method And Apparatus For Monitoring The Patency Of Vascular Grafts", issued April 10, 1990 to Holman, is directed to an implantable device which is anchored to the vessel using a collar (see Fig. 2). This reference is not considered anticipatory or suggestive of the proposed invention.

U.S. Patent No. 4,917,115, entitled "Pacing System And Method For Physiological Stimulation Of The Heart Utilizing Doppler Means", issued April 17, 1990 to Flammang, is directed to a cardiac pacing device.

U.S. Patent No. 4,926,875, entitled "Implantable And Extractable Biological Sensor Probe", issued May 22, 1990 to Rabinovitz, is directed to a probe body 10 which includes a doppler transducer to sense blood flow, and which is wrapped around the vessel and secured using suture 34 and release wire 28 (see Fig 1, 1b). To release the device wire 28 is pulled back, releasing suture 34 and allowing the probe 10 to unwrap. The device is then gently pulled out of the patient without surgery.

U.S. Patent No. 4,947,854, entitled "Epicardial Multifunctional Probe", issued August 14, 1990 to Rabinovitz, is directed to a implanted device which measures blood flow velocity and muscle thickening with two sensors.

Summary Of The Invention

Prior art implantable, extractable sensors are cumbersome to use and place undue stress on the vessel or organ during removal. Applicant's inventive device allows for easy placement on the monitoring site, most commonly a vessel, and allows for ease of removal without unduly stressing the vessel or organ.

Applicant's device is comprised of a probe body attached to a flexible tube. The probe body houses a doppler sensor for monitoring blood flow, typically through a vessel. A suture attachment wire extends through the flexible tube and terminates at the distal end of the probe body. A portion of the attachment wire is exposed and spaced a distance from the probe body so as to allow sutures to be attached, thereby securing the probe. To remove the device, the suture attachment wire is simply retracted until it is completely inside the flexible tubing, thereby

releasing the sutures. The device is then removed through the insertion wound by pulling on the flexible tubing.

Brief Description Of The Drawings

Fig. 1 is a simplified pictorial diagram of the preferred embodiment;

Fig. 2 is a perspective of Figure 1;

Fig. 3 is a fragmentary perspective view of the device implanted;

Fig. 4 is a fragmentary perspective view of the device during withdrawal;

Fig. 5 is a front elevational view of a second embodiment of the device with the artery shown in phantom dashed line;

Fig. 6 is a fragmentary sectional elevation taken along line 6-6 in Figure 5;

Fig. 7 shows a second method of suturing the device of Figure 5 in place;

Fig. 8 shows a third method of suturing the device of Figure 5 in place;

Fig. 9 shows a third embodiment of the invention, and

Fig. 10 is a fragmentary top elevational view of a fourth embodiment of the inventive device.

Description Of The Preferred Embodiments

While this invention may be embodied in many different forms, there are shown in the drawings and described in detail herein specific preferred embodiments of the invention. The present disclosure is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

Referring now to Figures 1 and 2, the inventive implantable and removable device or probe is shown generally at 10. The device is comprised of a transducer support 12 carried at the distal end 14 of the device, and which is connected to the proximal end 16 of the device by means of a flexible tube 18, as is well known in the art. The device is inserted into the body through insertion wound 20, then implanted on a vessel, such as an artery or vein. The device is primarily intended for use in monitoring blood flow through arteries or veins, but could also be used on other organs. The device is approximately 3/4 inch long and 3/8 inch in cross-section. The

device is intended to be secured onto the yessel such that it would lie generally axially along the vessel.

Referring now to Figures 3 and 4, transducer support 12 is shown secured to artery 22. In the preferred embodiment, a pair of release wires 24 and 26 extend through the flexible tubing 18 and are releasably attached to the front of transducer support 12 by insertion into wire channels 27 and 28. In the preferred embodiment, wires 24 and 26 are held in wire channels 27 and 28 by means of a compression spring (discussed more fully in connection with Figure 10). However, wires 24 and 26 or wire channels 27 and 28 could be sized so that the wires 24 and 26 were friction or compression loaded into wire channels 27 and 28.

As can be seen best in Figures 3 and 4, wires 24 and 26 are exposed at cut-outs 30, 32, 34 and 36, to allow sutures 38 to be attached to transducer support 12 to secure the transducer support 12 to the monitor site. The transducer is comprised of a generally flat piezoelectric crystal 40 which is mounted at an angle of between 5° and 85°, as is well known in the art. The preferred angle is approximately 50°, which provides a good compromise between measuring blood flow and vessel diameter, as is well known in the art. It should also be understood that the angle is measured between a line perpendicular to the vessel and the face of crystal 40. Lead wires 42 extend through flexible tubing 18 and are attached to electrical connector 44 (shown in Figure 2) for ease of connection to a monitoring device, as is well known in the art.

Release wires 24 and 26 can be extracted from channels 27 and 28 via detach access port 46 (shown in Figure 2). Cap 48 is removed, wires 24 and 26 are pulled out of channels 27 and 28, thereby releasing transducer support 12 from sutures 38, as shown in Figure 4. The transducer support 12 can then be withdrawn from the body by pulling on flexible tube 18. The transducer can be extracted through insertion wound 20 without the need for surgery.

Referring now to Figures 5 through 8, an alternate embodiment of the inventive device is shown. An elongate probe body 50 (best seen in Figure 6) is attached at the distal end of a flexible tube (not shown). Probe body 50 contains a wire channel 52 which has an opening 54 which opens to suture access space 56. The front end 58 of probe body 50 contains a wire channel 60 for frictional engagement with the distal end of release wire 62. Figure 5 shows how a series of sutures 38 can be looped around release wire 62, and secured to the vessel at 66 and 68. Figure 7 shows an

alternate attachment method in which the suture 38 is looped around the release wire 62, with both ends being attached on the same side of the vessel. Figure 8 shows how a suture could be looped around release wire 62 and then looped around the entire circumference of the vessel. In all cases, once release wire 62 is pulled from channel 60 and withdrawn back into channel 52, all sutures are disconnected from probe body 50, thereby freeing it for withdrawal.

Referring now to Figure 9, a third embodiment of the invention is shown of releasably securing the probe body (of Figure 6) or the transducer (of Figure 1) to the vessel. Reference numeral 70 refers to a balloon which can be inflated with saline solution, air or other suitable solution, via conduit 72. Balloon 70 would be inflated via a pilot cuff and luer fitting (not shown), which are well known in the art, then sutures 38 attached across balloon 70, thereby securing it in place at the monitoring site. To release the probe body, the balloon would be deflated, and the probe body would be withdrawn, leaving the sutures in place.

It was discovered through experimentation that bending the flexible tube 18 caused a ± 1 centimeter slack at the distal end 14 of the device. This slack would sometimes result in wires 24 and 26 being prematurely pulled out of wire channels 27 and 28. Figure 10 shows a fourth embodiment of the invention which is a modification to the release system designed to overcome this problem, discussed with reference to Figures 1 through 4, although it could be easily modified to work with the alternate embodiment discussed with reference to Figures 5 through 8. In this embodiment release wires 24 and 26 are in fact two ends of a single piece of wire. The wire is bent in half at loop end 80 and fixed to a loop plug 81 which is inside detach access port 46 (shown in Figure 2). A compression spring, shown schematically at 82 keeps a constant force on plug 81 via cap 48. This constant force aids in keeping the wire ends 24 and 26 firmly inside channels 27 and 28 while flexible tube 18 is being bent back and forth.

It is not necessary that release wires 24 and 26 be two ends of a single wire. Release wires 24 and 26 could be two separate wires connected to plug 81. It would also be possible to invert the embodiment shown in Figure 10. Wire channels 27 and 28 could be connected and loop end 80 could run through these channels, with the ends 24 and 26 extending back through the flexible tube. To release the device,

one end would be pulled until the other end had been pulled through both wire channels and back into the flexible tube 18, thereby releasing the device from any sutures.

It should be understood that the implanted device could carry any biological sensor, not just a doppler transducer for measuring blood flow. It should also be understood that all parts of the invention placed inside the body are made of a biocompatible material such as plastic or rubber, as is well known in the art. It should also be understood that the wire could be made of a flexible metal, plastic, or monofilament. Although in the embodiment described with reference to Figure 10, the wire must be flexible but rigid so as to transmit the force applied by spring 82.

This completes the description of the preferred and alternate embodiments of the invention. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.

WHAT IS CLAIMED IS:

1. An implantable, extractable probe for attachment to a vessel or organ, comprising:

(a) an elongate probe body having front and rear ends, the elongate probe body terminating in a flexible tube;

(b) at least one biological sensor attached to the probe body;

(c) at least one lead wire connected to the biological sensor, said lead wire extending through the flexible tube; and

(d) a suture attachment wire for attaching at least one suture to secure the probe body to a predetermined sensor site, the suture attachment wire being releasably connected to the front of the elongate probe body and extending through the flexible tube, at least a portion of the suture attachment wire extending between the front of the elongate probe body and the flexible tube such that it is spaced a predetermined distance from the probe body;

whereby the elongate probe body may be secured to a predetermined sensor site by attaching at least one suture to the suture attachment wire, such that when the suture attachment wire is released, the probe body is released for extraction from the body.

2. The implantable, extractable probe of claim 1 wherein the biological sensor is an ultrasound transducer.

3. The implantable, extractable probe of claim 1 wherein the biological sensor is attached to the probe body such that upon implantation, said sensor will rest at a 5 - 85° angle to the predetermined sensor site.

4. The implantable, extractable probe of claim 1 wherein the suture attachment wire is friction or compression loaded into a channel located in the front end of the probe body.

5. The implantable, extractable probe of claim 1 wherein the suture attachment wire is bent or looped to form two substantially equal lengths of wire, the two ends of the suture attachment wire being releasably connected to the front of the elongate probe body and extend through the flexible tube, at least a portion of each length of the suture attachment wire extending between the front of the elongate probe body and the flexible tube such that it is spaced a predetermined distance from the probe body.

6. The implantable, extractable probe of claim 4 wherein the suture attachment wire is bent or looped to form two substantially equal lengths of wire, the two ends of the suture attachment wire being releasably connected to the front of the elongate probe body and extend through the flexible tube, at least a portion of each length of the suture attachment wire extending between the front of the elongate probe body and the flexible tube such that it is spaced a predetermined distance from the probe body.

7. The implantable, extractable probe of claim 5 wherein the probe body has sides and is provided with two cut-outs on each side, and where one length of suture attachment wire extends through both cut-outs on one side of the probe body, while the other length of suture attachment wire extends through both cut-outs on the other side of the probe body, whereby the exposed lengths of suture attachment wire are spaced a predetermined distance from the probe body and provide suture attachment points to secure the probe in place at a monitoring site.

8. An implantable, extractable probe for attachment to a vessel or organ comprising:

(a) an elongate probe body having front and rear ends, the elongate probe body terminating in a flexible tube;

(b) at least one biological sensor attached to the probe body;

(c) at least one lead wire connected to the biological sensor, said lead wire extending through the flexible tube; and

(d) an inflatable balloon situated on the probe body;

whereby the elongate probe body may be releasably secured to a predetermined sensor site by at least one suture which is looped over the balloon, such that the probe body is secured by inflating the balloon and released for extraction from the body by deflating the balloon.

9. The implantable, extractable probe of claim 8 wherein the biological sensor is an ultrasound transducer.

10. The implantable, extractable probe of claim 9 wherein the biological sensor is attached to the probe body so that upon implantation, said sensor will rest at a 5 - 85° angle to the predetermined sensor site.

Fig.1

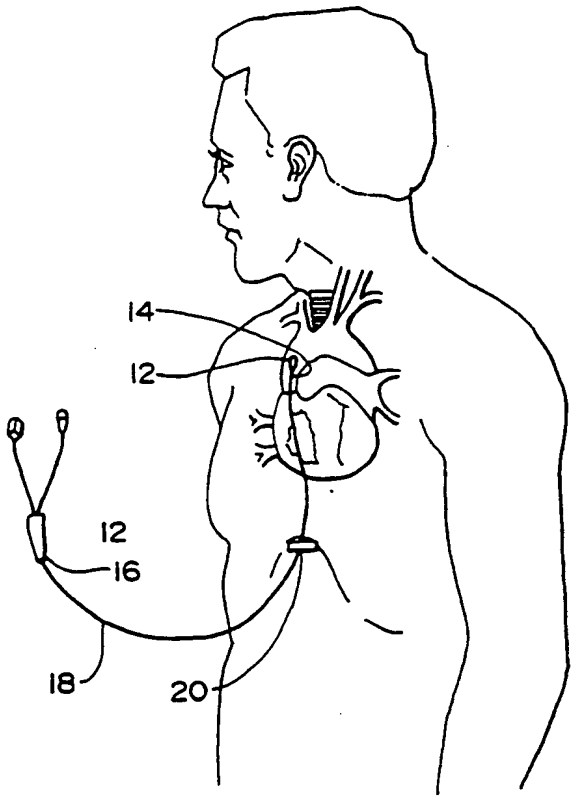


Fig.2

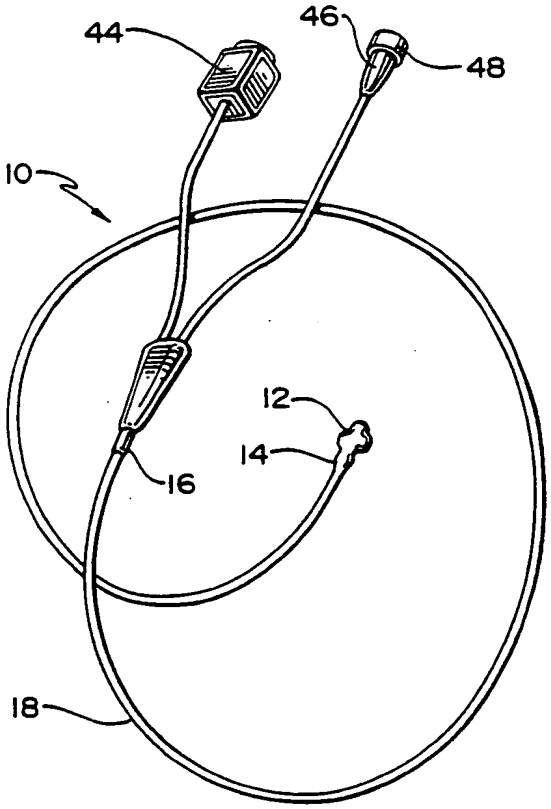


Fig.3

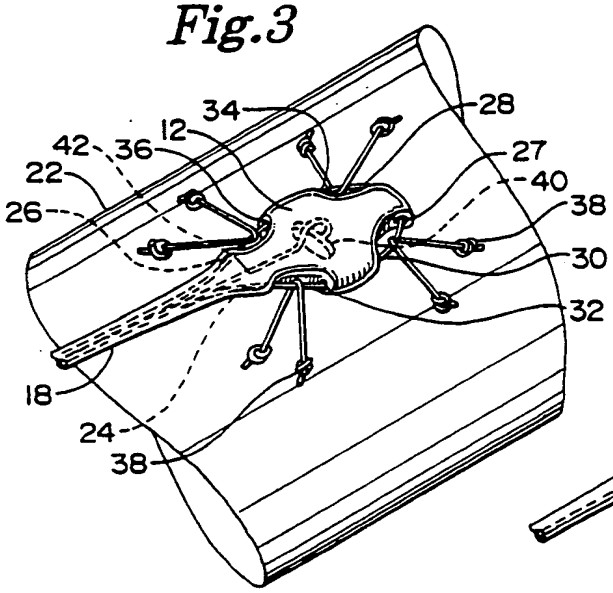


Fig.4

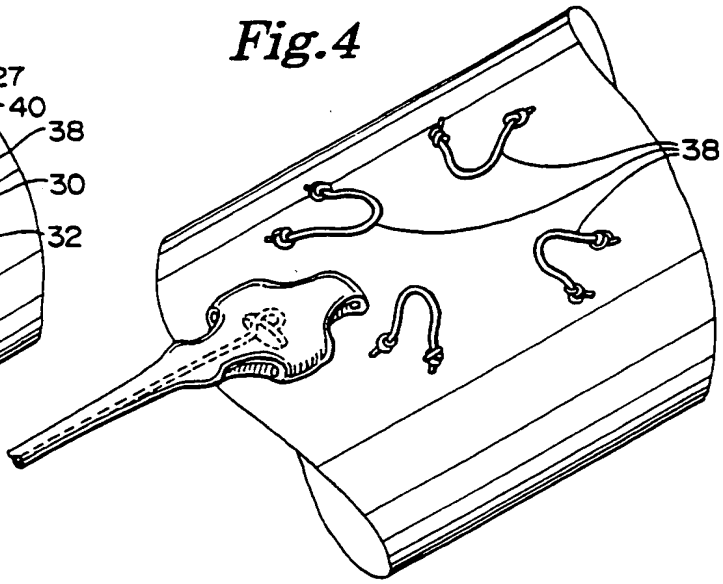


Fig.5

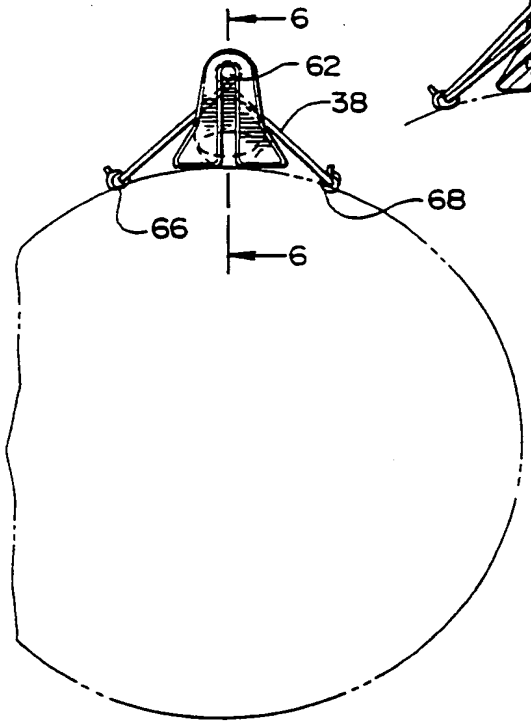


Fig.7

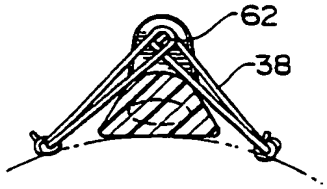


Fig.8

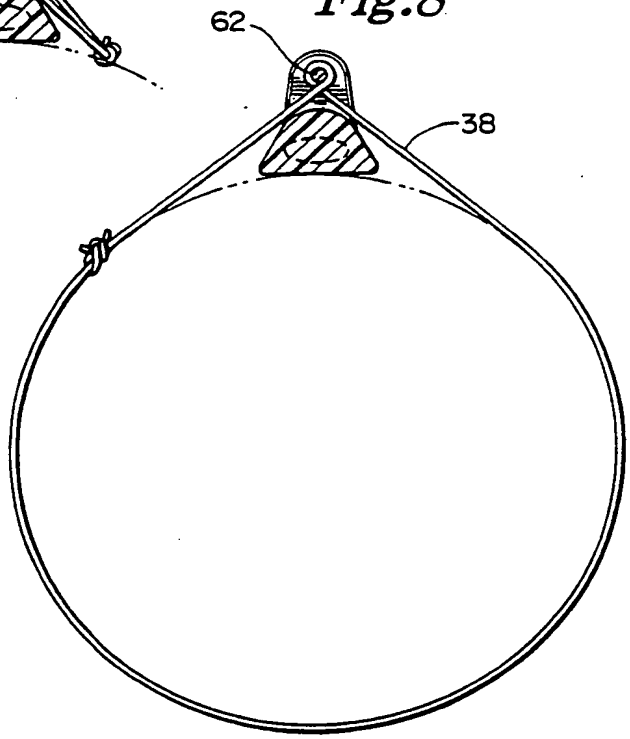


Fig.6

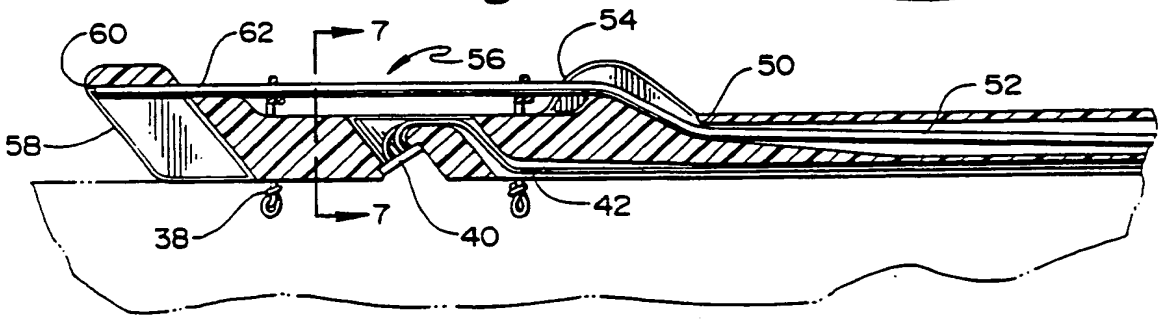


Fig.9

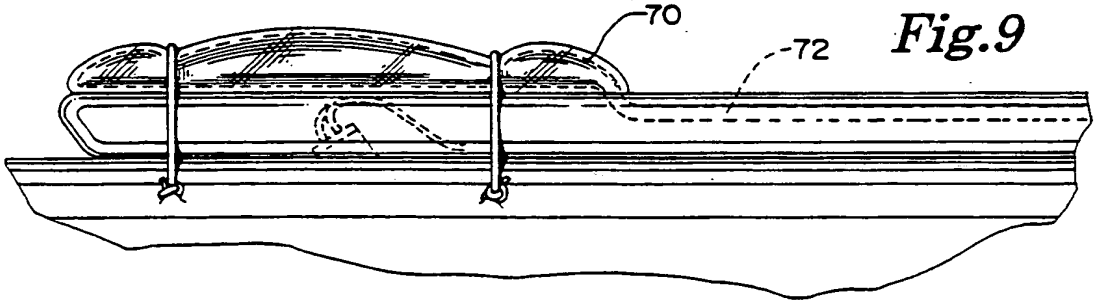
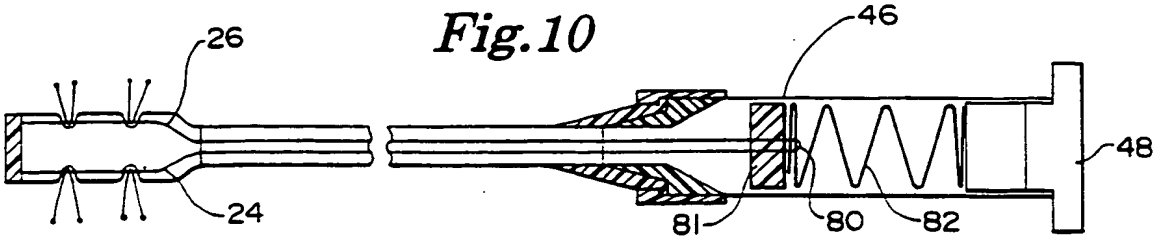


Fig.10



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/04542

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 5/026, 8/06
US CL :128/662.04, 691
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/661.08-661.1, 662.01, 662.03, 662.05, 662.06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US, A, 4,926,875 (RABINOVITZ ET AL.) 22 May 1990, see entire document.	1-4 — 5-10
X — Y	US, A, 4,947,854 (RABINOVITZ ET AL.) 14 August 1990, see entire document.	1-4 — 5-10
Y	US, A, 4,541,433 (BAUDINO) 17 September 1985, see figure 2.	5-7
Y	US, A, 4,722,347 (ABRAMS ET AL.) 02 February 1988, see column 6, lines 51-62.	8-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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